## TCT-19

### Randomized Trial of Proximal- vs. Distal Cerebral Protection on Microembolization During Carotid Artery Stenting in Patients with High-risk Lipid Plaque

*Piero Montorsi[1], Luigi Caputi[2], Stefano Galli[1], Paolo Ravagnani[1], Costanza Boiti[1], Giovanni Ballerini[1], Marco Agrifoglio[1], Daniela Trabattoni[1], Franco Fabbiocchi[1], Antonio L Bartorelli[1]*
*[1]Institute of cardiology University of Milan, Milan, Italy[2]Neurological Institute Carlo Besta, Milan, Italy*

**Background:** Cerebral embolization is the major complication of carotid artery stenting (CAS). Proximal protection has been found to offer a better protection than filter in unselected patients scheduled for CAS. To compare the efficacy of proximal- (MOMA, Invatec, Italy) vs. distal (Filterwire EZ, Boston Scientific, USA) protection in patients with high risk lipid plaque.
**Methods:** Fifty-three consecutive patients with carotid artery stenosis (>70% if asymptomatic and >50% stenosis if symptomatic by Doppler US) and lipid plaque by CT-angiography (≤50 Hounsfield unit) were randomized to CAS with MOMA (n=26) or Filterwire EZ (n=27). Microembolic signals (MES) were detected by trans-cranial Doppler of the ipsilateral middle cerebral artery in the following 6 phases: 1) lesion wiring 2) Predilation 3) Stent crossing. 4) Stent deployment. 5) Post-dilation and 6) Protection device retrival/deflation. Standard CAS technique and anticoagulation/antiplatelet treatment were used in all patients. Predilation was left at operator's discretion. Carotid Wallstent was used in all cases.
**Results:** Patient and angiographic target lesion characteristics were not different between the 2 groups. Hounsfield units value was similar in both groups: 31±9 vs. 31±11, p=NS. "High-surgical risk" characteristics were detected in 41% of patients.CAS was successful in all cases. No intolerance to MOMA was detected. Two in-hospital cerebral complications occurred in the Filterwire EZ group (1 retinal embolism and 1 TIA at 48 hours). Number of pts with detectable MES was significantly greater in filter vs. MOMA group in phase 3 to 5 (100% vs. 27%, p=0.000). MES number for each CAS phases are reported in the Table.

| | Filterwire EZ | MOMA | p Value |
|---|---|---|---|
| Lesion wiring | 20.93±14.2 | 5.77±9.3 | <0.0001 |
| Pre-dilation | 8.43±5.1 | 2.20±5.2 | 0.26 |
| Stent crossing of the lesion | 30.59±30.7 | 1±2.2 | <0.0001 |
| Stent deployment | 24.37±15.7 | 1.46±3.9 | <0.0001 |
| Stent post-dilation | 20.0±14.7 | 2.73±6.2 | <0.0001 |
| Device retrieval/deflation | 3.63±4.5 | 10.73±10.4 | <0.0001 |
| Mean MES /patient | 19.64±10.7 | 4.22±3.5 | <0.0001 |
| Total MES | 101.7±53.4 | 22.54±18.8 | <0.0001 |
| Predilation performed in 7 pts with Filterwire EZ and 10 pts with MOMA | | | |

**Conclusions:** CAS with MOMA led to significantly lower MES counts supporting the safety and efficacy of this type of protection even in patients with high risk lipidic plaque.

## TCT-20

### Neuropsychological Changes Following Carotid Artery Stenting in Asymptomatic Patients

*Oscar A Mendiz, Nicolás Fabro, Gustavo Lev, Analía Calle, Luciano Sposato, Elena Gleichgerrcht, Carlos Fava, Facundo Manes, Leon Valdivieso*
*Fundación Favaloro, Buenos Aires, Argentina*

**Aim:** To investigate the **changes in neuropsychological performance** following elective carotid artery stenting (CAS) in asymptomatic patients (APs).
**Methods:** 43 APs (Mean age = 71, *SD* = 8; 65% male) were treated with CAS under cerebral protection (Mean time = 6.4 min, *SD* = 1.2). APs received a total of 47 procedures (4 had staged bilateral CAS) and were assessed at baseline and post-procedure (three months apart) using
Echo-Doppler, CT scan, neurological evaluation, and a comprehensive neuropsychological battery.
**Outcomes:** Angiographic success was achieved in all procedures; 1 AP suffered a TIA, and another had a fatal hemorrhagic stroke two weeks after index procedure. Mean hospitalization time was 1.2 days (SD = 1.3). Three-month follow-up revealed significant improvement in verbal (RAVLT learning: $t_{45} = -4.17$, $p < .001$; RAVLT delayed score: $t_{45} = -3.2$, $p < .001$) and visual (ROCF delayed: $t_{42} = -3.65$, $p < .001$) memory as well as in executive functions (TMT-B: $t_{41} = -3.13$, $p < .001$; WCST: $t_{37} = -2.54$, $p = .015$; speed processing: $t_{41} = -2.60$, $p = .013$) although no significant differences were found on pre- & post-procedural mood scores.
**Conclusion:** Our results reveal that CAS improves cognitive performance in supposedly asymptomatic patients, suggesting that such "asymptomatic" nature may in fact be overlooking at the cognitive profile of this patient population. Including comprehensive cognitive assessment of CAS candidate patients is essential in order to determine procedural outcome.

## TCT-21

### Percutaneous Transluminal Angioplasty and Stenting of Extracranial Vertebral Artery Stenoses

*Michel Henry[1], Isabelle Henry[2], Antonios Polydorou[3], Michèle Hugel[1]*
*[1]Cabinet de Cardiologie, Nancy, France[2]Polyclinique Bois Bernard, Bois Bernard, France[3]Apollo Clinic, Athens, Greece*

**Purpose:** To evaluate the safety and efficiency of vertebral angioplasty and stenting (VAS) in symptomatic patients.
**Material and methods:** 97 angioplasties in 91 pts (M:69) mean age 68,2 ± 6,8 years (22-84) left 55. All pts had multivascular diseases: carotid (CA):61, subclavian (SA): 24, coronary:62.... Atheromatous lesions: 95, inflammatory: 2. Mean lesion length: 9,6 +/- 2,8 mm. Mean % stenosis 83.1 ± 7.8, mean arterial diameter : 4,8 ± 0,6 mm (4-6). 89 lesions at VO segment (ostium), 6 at V1 and 2 at V2 segments. Indications for angioplasty: dizziness (91), bilateral weakness (11), visual changes (11), diplopia (10), drop attacks (19), TIA (12), ataxia (5). A protection device (filter) used in 8 pts. 17 SA angioplasties performed at the same time of VAS, 7 CA. All angioplasties performed by femoral approach, 4 by brachial approaches after failure of femoral approach. (2 successes).
**Results:** Technical success 95/97 (98%). Defined. 6 lesions treated by angioplasty alone: 3 VO (first 3 pts. 2 V1, 1 V2 lesion). 1 pt (inflammatory disease) treated by cutting balloon alone. 84 lesions treated with stents (direct stenting: 69). Peripheral balloon expandable stents (n=19), self expandable stents (n=4 for 3 V1 and one V2 lesions). 65 coronary stents (11 DES). 1 pt developed a TIA during the procedure. No neurological complications at 30 days Clinical success 89/91 (98%)
Post-procedure arterial diameter: 4,55 ± 0,8 mm (4-6). Mean residual stenosis 2,2 ± 3,5 %.
In 8 pts treated with protection devices, visible debris removed in 6 (4 Filterwire, 2 Fibernet) with the same amount of debris as during Carotid Stenting) 6 pts (9%) developed symptomatic restenosis during the follow-up (mean: 32.2±28.8 months). 3 after PTA alone, 1 after PTA and stent (1 occlusion treated medically, 5 stenoses successfully treated with PTA). No restenosis after DES implantation at 1 year.
**Conclusion:** VAS can be performed safely and effectively with a high technical success rate, a low complication rate, a low restenosis rate and a durable clinical success in patients with symptomatic VA stenosis. Stents seem to improve immediate and long-term results. The role of protection devices has to be discussed.

## TCT-22

### Mechanical Embolectomy For Large Vessel Ischemic Strokes

*Mark J Abelson*
*Veregelegen Medi Clinic, Somerset West, South Africa*

**Introduction:** Large vessel (proximal middle cerebral, internal carotid and basilar arteries) acute ischemic stroke has a poor outcome with reported mortalities of 30 -90%. The survivors are often left with significant neurological impairment. Intra-venous thrombolysis is often contra-indicated and if given, usually ineffective. Mechanical embolectomy is an option in these patients and may be performed by an interventional cardiologist experienced in carotid interventions.
**Method:** From January 2007 to September 2009 consecutive stroke patients were assessed by the stroke physician and, if eligible, referred for possible mechanical embolectomy using the Merci Retriever (Concentric Medical, Mountain View, California, USA). Intra-arterial thrombolysis was permitted. All procedures were done by a single cardiologist. Patient information, procedural characteristics and clinical outcomes at 90 days were collected by retrospective chart review.
**Results:** A total of 22 patients (mean age 66.9 years) were referred for emergency cerebral angiography with 17 undergoing mechanical embolectomy. Intra-arterial thrombolysis was administered in nine patients The mean National Institute of Health Stroke Scale (NIHSS) score was 20.1 and the mean stroke duration was 284 minutes. Recanalization was successful in 15 (88%) patients. Of these 15 patients ten (59%) had a good outcome (modified Rankin Score ≤ 2 @ 90 days) and 2 died (mortality 13%). Three patients had significant intra-cerebral hemorrhage (1 died and 2 had a good outcome). There were no other major adverse events. Of the 7 patients where recanalization failed, 3 died (mortality 43%) and only 1 had a good outcome (14%).
**Conclusions:** For patients with large vessel occlusion strokes where intra-venous thrombolysis was either contra-indicated or had failed, mechanical embolectomy performed by an interventional cardiologist had a high recanalization rate with an acceptable clinical outcome and safety profile.

## TCT-23

### Endovascular Treatment of Thoracic Aortic Disease: Eleven Years Follow-Up

*Emanuela de Cillis, Giovanni Rubino, Lugi de Luca Tupputi Schinosa, Alessandro S Bortone*
*Institute of Cardiac Surgery - University of Bari, Bari, Italy*

**Background:** The aim of this perspective study is to investigate efficacy and long-term results of stent graft treatment for diseases of descending thoracic aorta.
Methods: From March 1999 to May 2010, 184 patients (156 male and 28 female, mean age 62±14 years) were enrolled. They were divided into 3 groups: aneurysms (65, Group A: 9 with acute rupture), post-traumatic lesions (57, Group B: 38 acute and 19 chronic) and complicated type B dissection (62, Group C: 43 acute and 19 chronic). All patients underwent CT scan and angiography as preoperative assessment.
**Results:** An optimal deployment with exclusion of the aneurysm, repair of the aortic lesions in post-traumatic and closure of the primary entry tear in dissection was achieved acutely in 98.4% (184/187) of the patients that were discharged in good conditions within 5 days. No spinal cord injuries were observed. The follow-up (average 52 months, range 1 to 134), performed with serial CT scans, was 100% complete. Stent graft-related complications were detected in 5.4% (10/184) of the patients: Two re-lining for symptomatic type III endoleak in Group A (3.1%). Two asymptomatic connecting bar rupture in Group B (3.5%). Four distal asymptomatic retrograde blood flow inside the false lumen in Group C (6.4%) and 2 retrograde type A dissection in the same group (3.2%) successfully treated by conventional surgery approach. Only in 2 patients in Group C (3.2%) a proximal new entry tear was detected during the follow-up successfully treated by a second endoprosthesis. A total of 5 hospital deaths resulted in an overall operative mortality of 2.7%. Ten patients (5.4%) died during the follow-up: Four of them for co-morbidities (2.2%), whereas 6 patients (3.2%) for disease progression.
**Conclusions:** Endovascular treatment of thoracic aortic diseases, even in the acute phase, may represent a valid option with a low mortality rate. Moreover, the efficacy is proved in the long-term follow-up.

## TCT-24

### A New Protection Device: the Fibernet. First Human Use in Carotid, Renal and Peripheral Interventions

*Michel Henry[1], Antonios Polydorou[2], Isabelle Henry[3], Amanda Polydorou[2], Michèle Hugel[1]*
*[1]Cabinet de Cardiologie, Nancy, France[2]Apollo Clinic, Athens, Greece[3]Polyclinique Bois Bernard, Bois Bernard, France*

**Background:** It is now clear that atheroemboli are the rule in any intervention in atherosclerotic disease and seems the root cause of any procedural complications. Embolic Protection Devices (EPD) are widely used in carotid and several reports pointed out their role in other peripheral procedures (renal, leg,vertebral arteries). However current EPD have significant limitations, which may be addressed by a new EPD the Fibernet ™ (Lumen Biomedical Inc., Plymouth Mass.)
**Methods:** The system consists of a 3 dimensional expandable filter made of unique fibers, which expand radially to fill the lumen, mounted onto a 190 cm long 0.014 wire. No delivery sheath required. Low crossing profile (1,7 - 2,9 F). Retrieval catheter with focal suction during device removal allowing meticulous cleaning of the vessel. The filter can fill vessels from 1,75 to 7 mm and capture particles as small as 40 microns without compromising the flow.
**Results:** We performed:
- 68 carotid Angioplasty Stenting. Technical success 98 %. 30-day complications: 1 minor stroke (1,5%). Debris analysis done in 34 Fibernet procedures and compared with 14 other filters. Visible